THE OFFICIAL JOURNAL OF THE BRITISH DIETETIC ASSOCIATION

Journal of Human Nutrition and Dietetics

PROFESSIONAL GUIDELINE

Royal College of Physicians Intercollegiate Stroke Working Party evidence-based guidelines for the nutritional support of patients who have had a stroke

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Keywords
artificial feeding, dysphagia, guidelines, malnutrition, nutritional support, stroke.

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How to cite this article
Gomes F., Hookway C. & Weekes C.E. (2013) Royal College of Physicians Intercollegiate Stroke Working Party evidence-based guidelines for the nutritional support of patients who have had a stroke. *J Hum Nutr Diet*. doi:10.1111/jhn.12185

Abstract

Background: Stroke affects 15 million people each year worldwide and is one of the world's leading causes of death and physical disability. Stroke can result in a decline in nutritional status and this is associated with increased mortality and poor outcomes. The present work aimed to systematically review key aspects of the nutritional support of stroke patients at risk of malnutrition and to provide evidence-based guidelines for use in clinical practice. The work was conducted as part of the process to develop the 4th edition of the Royal College of Physicians' (RCP) 'National Clinical Guideline (NCG) for Stroke'.

Methods: Questions were generated by the search team, together with contributions from members of the Virtual Stroke Group and the RCP Intercollegiate Stroke Working Party Guideline Development Group. Six questions covering several areas of nutritional support after stroke were defined and searches were conducted through to 31 October 2011 using five electronic databases (Embase, Medline, CINAHL, Cochrane Library and Web of Science). All included studies were assessed for quality and risk of bias using the van Tulder criteria for randomised controlled trials (RCTs) and the Quorum criteria for systematic reviews.

Results: In total, 4215 abstracts were identified, 24 papers were reviewed and 13 systematic reviews and RCTs were included to provide evidence for the nutritional support components of the guidelines. For each question, evidence statements, recommendations and practical considerations were developed.

Conclusions: This systematic review process has resulted in the development of evidence-based guidelines for use in clinical practice and has identified areas for further research.

Introduction

Every year, 15 million people worldwide suffer a stroke and nearly six million die (World Health Organization, 2002). In the UK, there are approximately 152 000 strokes in a year and, in 2010, stroke was the fourth largest cause of death after cancer, heart disease and respiratory disease, causing almost 50 000 deaths (Townsend *et al.*, 2012). Stroke is the second leading cause of disability worldwide, after dementia (Sousa *et al.*, 2009), resulting in five million people being permanently disabled annually (World Health Organization, 2004) and, in the UK, more than half of all stroke survivors are left dependent on others for everyday activities (Royal College of Physicians, 2011).

After stroke, a number of stroke-specific and generic factors can result in decline in nutritional status. The most notable cause of poor oral intake (aside from

altered consciousness) is oropharyngeal dysphagia but additional factors could include fatigue, hemiplegia, depression, visual spatial neglect, reduced mobility and ability to self-feed, taste changes, reduced appetite and poor oral health (Dennis, 2000).

There is some variation in the reported prevalence of malnutrition in patients admitted to hospital following a stroke, from 6% to 62% (Unosson *et al.*, 1994; Gariballa *et al.*, 1998c; Foley *et al.*, 2009), partly as a result of different criteria being used to define malnutrition. Being malnourished on admission is, however, associated with an increased risk of mortality and poor outcome (Dennis, 2003; Martineau *et al.*, 2005). Furthermore, up to one quarter of patients become more malnourished in the first weeks after a stroke (Davalos *et al.*, 1996; Yoo *et al.*, 2008) and this is associated with increased mortality (Davalos *et al.*, 1996) and complications (Yoo *et al.*, 2008), as well as poorer functional and clinical outcomes (Davalos *et al.*, 1996; Gariballa *et al.*, 1998a). Weight loss, feeding and swallowing problems can persist for many months after a stroke with the potential to have an adverse impact on nutritional status and outcome if not effectively managed (Finestone *et al.*, 2002; Perry, 2004; Jonsson *et al.*, 2008).

In the light of poor outcomes being associated with malnutrition and/or declining nutritional status after stroke, the present work aimed to systematically review key aspects of the nutritional support of nutritionally vulnerable patients who have had a stroke, with the aim of providing evidence-based guidelines for nutritional management. The searches and recommendations presented here were undertaken in preparation for the 4th edition of the Royal College of Physicians Intercollegiate Stroke Working Party (RCP/ISWP) national clinical guidelines for stroke (RCP/ISWP, 2012).

Materials and methods

The process started with a review of the search questions originally submitted for the 3rd edition of the 'National clinical guidelines for stroke' (RCP/ISWP, 2008). The Guideline Development Group (GDG) recommended continued inclusion of relevant recommendations from the National Institute for Health and Care Excellence (NICE) guidelines on nutritional support for adults (NICE, 2006) (e.g. need for routine nutrition screening).

To identify other potentially relevant search questions, a request was sent out to dietitians working in stroke care via the Virtual Stroke Group (VSG) of the British Dietetic Association. Search questions were developed by the search team (CH, FG, CEW), taking into account the views of the VSG members, together with the GDG. Some of the previous questions from the 3rd edition were included, although new ones were also added to reflect changes in clinical practice.

Generic inclusion and exclusion criteria regarding participants, outcome measures and study type were determined by the GDG. Nutrition-specific criteria were determined by the authors, in collaboration with the GDG (Table 1).

Search terms were defined by the search team with the assistance of a specialist librarian (for search terms, see Supporting information, Data S1). Searches were conducted through to 31 October 2011 by one author (FG) using five electronic databases:

- Cochrane Library
- Medline
- Embase
- CINAHL
- Web of Science

All titles and abstracts were reviewed by one person (CEW). Any potentially relevant studies identified were

Table 1 Inclusion and exclusion criteria

Criteria	Inclusion	Exclusion
Participants	Adults aged ≥16 years Confirmed diagnosis of acute stroke	Aged <16 years Transient ischaemic attack
Interventions	Topic specific	
Comparisons	Usual care	
Outcome measures	Mortality Morbidity (risk of hospital admission or readmission and length of hospital stay) Change in nutritional status (e.g. weight and body mass index) Change in clinical function (e.g. immune function, respiratory function) Change in functional status (e.g. Barthel score, modified Rankin Score) Quality of life (e.g. EuroQol-5D) Cost-effectiveness	
Types of study	Systematic reviews, randomised controlled trials and quasi-randomised controlled trials English language	Nonsystematic reviews, observational studies, audits, case studies

assessed independently by two reviewers (CEW and CH) against the inclusion criteria defined for each question. All potentially eligible studies were evaluated by two reviewers (CEW or CH plus one additional reviewer) and any disagreements were resolved by discussion with a third person. For all included studies, data were extracted by the reviewers using a standard pro forma developed by the search team.

The risk of bias and the methodological quality of all systematic reviews were assessed using the Quorum criteria (Moher *et al.*, 1999) and the quality of all randomised controlled trials was assessed using standard criteria (van Tulder *et al.*, 2003).

Evidence tables for each study were submitted to the GDG at regular intervals for review and final approval. Recommendations were then written based upon the results of the included studies. In the absence of evidence from studies of sufficient quality, consensus statements were derived by the search team and submitted for final review and approval by the GDG.

The levels of evidence supporting each recommendation (related to the design of each study) and the grades of recommendation (related to the strength of the supporting evidence) were based on the criteria used by the Scottish Intercollegiate Guidelines Network (SIGN, 2010). The grading system varies from A to D, where A corresponds to the highest quality of evidence (e.g. high quality meta-analysis) and D corresponds to the lowest [e.g. expert opinion and good practice point (GPP)].

The draft guidelines were reviewed during regular meetings of the full multidisciplinary RCP/ISWP throughout 2010 and 2011. The nutrition support components were reviewed as part of the whole draft guideline document in spring 2012 by a variety of clinical and academic professionals, patient organisations and stakeholders (RCP/ISWP, 2012).

Results

Table 2 provides a summary of the number of abstracts identified, papers reviewed and the number of systematic reviews and randomised controlled trials (RCTs) included, thus providing evidence for the nutritional support components of the guidelines. Tables 3 to 7 provide summaries of the study design, participants, interventions, duration, outcome measures and results for each of the trials included for each question.

Included studies and evidence statements

A1 In patients with acute stroke who can consume adequate fluids orally and are assessed as at nutritional risk (using a validated method), do oral nutritional supplements (ONS) reduce morbidity and/or mortality and/or improve functional status or quality of life compared to diet alone?

One large, good quality RCT, the FOOD Trial (Dennis *et al.*, 2005b), and two smaller RCTs of moderate quality (Gariballa *et al.*, 1998b; Rabadi *et al.*, 2008) met the inclusion criteria. The two smaller RCTs (Gariballa *et al.*, 1998b; Rabadi *et al.*, 2008) evaluated the effect of providing ONS to stroke patients identified as malnourished or at risk of malnutrition on mortality, dietary intake, body weight, functional status, length of hospital stay and the proportion of patients discharged home (Table 3). The smallest trial ($n = 20$) evaluated the effects of ONS in addition to normal hospital diet compared to normal hospital diet alone over a period of 4 weeks. At 12 weeks, significant differences in energy intake, serum iron and albumin in favour of the intervention group were observed but there were no differences in any other outcomes (Gariballa *et al.*, 1998b). A larger trial ($n = 102$) compared the effects of a high energy, high protein ONS with a standard energy and protein ONS throughout hospital stay on functional independence measure (FIM) scores, length of hospital stay, timed walk tests and body weight (Rabadi *et al.*, 2008). In this study, there were significant differences between the groups in favour of the high energy, high protein supplemented group in some outcomes (FIM total score, FIM motor score, 2- and 6-min walk tests) but not in others (FIM cognition score, length of hospital stay and body weight). The largest trial ($n = 4023$) evaluated the effects of routine provision of ONS in addition to normal hospital diet (irrespective of nutritional status) with normal hospital diet alone throughout hospital stay, on mortality, poor outcome (i.e. death or dependency), in-hospital complications, length of hospital stay, discharge destination, quality of life and adverse events (Dennis *et al.*, 2005b). The full report of this study is available in a Health Technology Assessment monograph (Dennis *et al.*, 2006). In this trial, there were no statistically significant differences between the groups in any of the outcomes. Notwithstanding the size of this trial, there were several limitations to the study design that might at least partially explain this lack of effect. The primary goal of nutritional support is to increase nutritional intake and thereby improve or maintain nutritional status yet, although nutritional status was estimated at admission, no standardised method of nutritional assessment was applied. Furthermore, neither nutritional status, nor intake were monitored during the intervention period or at follow-up. In the absence of such data, it is not possible to determine whether the intervention group achieved a higher nutritional intake than the control group.

One other RCT ($n = 170$) of moderate quality was identified (Ha *et al.*, 2010a,b). Although this study did

Table 2 Search questions, number of abstracts identified, papers reviewed, systematic reviews and randomised controlled trials (RCTs) included

Search questions	Abstracts identified	Papers reviewed	Trials excluded	Systematic reviews included	RCTs included
A1 – In patients with acute stroke who can consume adequate fluids orally and are assessed as at nutritional risk (using a validated method), do oral nutritional supplements reduce morbidity and/or mortality and/or improve functional status or quality of life compared to diet alone?	2084	6	2	0	4
A2 – In patients with acute stroke who are unable to consume adequate fluids orally and are assessed as at nutritional risk (using a validated method), does enteral nutrition via a nasogastric tube (NGT) reduce mortality and/or morbidity and/or improve functional status or quality of life compared to a modified texture diet?	510	2	2	0	0
A3 – In patients with acute stroke who are unable to consume adequate fluids orally and are assessed as at nutritional risk using a validated method, does enteral nutrition via a gastrostomy reduce mortality and/or morbidity and/or improve functional status or quality of life compared to enteral nutrition via a NGT?	756	2	1	1	3
A4 – In patients with acute stroke who are receiving enteral nutrition via a NGT, does a nasal bridle, mittens or other restraining device increase the length of time the NGT is *in situ* and reduce mortality and morbidity or prevent early feeding via a gastrostomy compared to not using any devices?	34	1	0	0	1
A5 – In patients with acute stroke who require enteral tube feeding does feeding into the small bowel reduce the risk of aspiration compared to intragastric feeding?	570	2	0	1	2
A6 – In patients with acute stroke who are unable to consume sufficient fluids orally and are assessed as at nutritional risk, does supplementing a texture modified diet with enteral tube feeding (nasogastric or gastrostomy) and/or oral nutritional supplements reduce mortality and/or morbidity and/or improve functional status or quality of life compared to modified texture alone?	261	11	10	1	0

not meet the inclusion criteria (i.e. also included patients that cannot consume adequate fluids orally), it provides relevant information for this question. This trial evaluated the effect of an individualised nutrition treatment plan (including ONS and enteral tube feeding as required) compared to usual care in stroke patients identified as malnourished or at risk of malnutrition using a modified version of the Malnutrition Universal Screening Tool (MUST) (Elia, 2003), on energy and protein intake, body weight, quality of life, handgrip strength and length of hospital stay. Significant differences between the groups in favour of intervention were observed in energy and protein intake, weight change and change in handgrip strength but not in length of hospital stay. Although there were within group improvements in some domains of the quality of life questionnaire in the intervention group, these results should be interpreted with caution because 46 (27%) of the questionnaires were incomplete.

In discussion with the GDG, and taking into account the relevant NICE guidelines (NICE, 2006), the following evidence statements were developed.

A1.1 Patients should be screened for malnutrition and the risk of malnutrition at the time of admission and at least weekly thereafter. Screening should be undertaken by trained staff using a structured assessment such as the MUST [NICE guidelines, graded D (GPP)]

A1.2 Nutritional support should be initiated for people with stroke who are at risk of malnutrition. This may include specialist dietary advice, ONSs and/or enteral tube feeding (RCP/ISWP, graded C)

A1.3 Routine oral nutritional supplements are not recommended for people with acute stroke who are adequately nourished on admission (RCP/ISWP, graded B)

A1.4 Stroke patients with difficulties self-feeding should be assessed and provided with the appropriate equipment and assistance (including physical help and verbal encour-

Table 3 Description of studies included for question A1: provision of oral nutritional supplements for patients who are malnourished or at risk

Study	Study design	Participants	Intervention, duration and outcome measures	Results	Quality assessment
Gariballa *et al.* (1998b)	Randomised controlled trial (RCT) single blind, single site (n = 42)	Conscious, no dysphagia, in the first week after onset of ischaemic stroke Anthropometric evidence of undernutrition	*Intervention* (n = 20) Oral nutritional supplements (ONS) in addition to normal hospital food *Control* (n = 20) Normal hospital food *Duration* 12 weeks *Outcome measures* Energy intake Protein intake Body weight Proportion discharged home Barthel score Serum albumin Iron levels Mortality	40 (95%) included in analysis (n = 2 failed to complete) *Energy intake* Significantly greater intake in the supplemented group (7.56 MJ versus 4.54 MJ day^{-1}; $P < 0.0001$) *Protein intake* Significantly greater intake in supplemented group (65.1 versus 44.1 g day^{-1}; $P < 0.001$) *Weight:* NS *Proportion discharged home:* NS *Barthel scores:* NS *Serum albumin* Significant difference in mean change (95% CI = −5.57 to −0.4; $P = 0.025$) *Iron levels* Significant difference in mean change (95% CI = −10.0 to −0.6; $P = 0.030$) *Mortality:* NS	Small sample size Baseline difference in serum albumin and iron levels were not used as covariates Within group variation observed in the length of time supplementation was taken
Dennis *et al.* (2005b)	Multicentre open-label RCT (n = 4023 randomised and intention to treat analysis)	Admitted to hospital within 7 days of a stroke and clinician uncertain about the best feeding policy Exclusion: transient ischaemic attack or minor stroke 77% considered normal weight; 9% considered malnourished (variety of assessment methods used)	*Intervention* (n = 2016) ONS (i.e. 3 × 120-mL doses) [6.3 kJ (1.5 kcal) mL^{-1}] in addition to normal hospital diet *Control* (n = 2007) Normal hospital diet *Duration* Intervention received only until hospital discharge Length of follow-up 6 months *Outcome measures* Mortality Poor outcome (i.e. modified Rankin score = 3–5) In-hospital complications Length of hospital stay Discharge destination Quality of life Adverse events	4023 (100%) included in intention to treat analysis (Intervention n = 12 and Control n = 7 failed to complete) *Mortality & disability*: NS *In-hospital complications*: NS *Length of hospital stay and discharge destination*: NS *Quality of life (EuroQol-5D)*: NS in any of the scales *Adverse events* No serious life-threatening events	A variety of methods were used to assess nutritional status. In 2967 (84%) patients an informal assessment was used; weight or Body mass index was used in 702 (19.9%) patients and a dietitian's assessment in 487 (13.8%); no data were collected on dietary intake

Table 3 *(Continued)*

Study	Study design	Participants	Intervention, duration and outcome measures	Results	Quality assessment
Rabadi *et al.* (2008)	Single centre RCT (n = 116)	Patients aged >60 years recruited within 4 weeks of ischaemic or haemorrhagic stroke on admission to a rehabilitation unit Nutritional status defined using the standards of the American Dietetic Association (i.e. >2.5% weight loss within 2 weeks after stroke)	*Intervention* (n = 58) Received hospital diet plus one nutrient dense (1.00 MJ; 11 g protein) ONS per day *Control* (n = 58) Received hospital diet plus one standard [531 kJ (127 kcal); 5 g protein] ONS per day *Duration* Participants received ONS until hospital discharge *Outcome measures* Primary outcome Change in Functional independence measure (FIM) total score Secondary outcomes FIM motor subscore FIM cognitive subscore Length of hospital stay 2-min timed walk test 6-min timed walk test Body weight	102 (89%) completed the study (n = 14 failed to complete) Primary outcome Significant differences in favour of intervention in FIM total score [22.94 (SD 11.79) versus 31.49 (SD 14.26); P = 0.001] Secondary outcomes Significant differences in the following: FIM motor score [16.71 (SD 9.64) versus 24.25 (SD 11.83); P = 0.001] 2-min walk test [43.98 (SD 62.46) versus 101.60 (SD 79.41); P < 0.001] 6-min walk test [170.59 (SD 198.61) versus 299.28 (SD 201.54); P < 0.001]. Fewer patients in the control group were discharged home (43% versus 63%; P = 0.05) *FIM cognitive score, length of stay or body weight*: NS	Randomisation method not stated; treatment allocation concealed in opaque envelopes; double-blind trial; length of intervention varied with length of hospital stay
Ha *et al.* (2010a,b)	Single centre RCT (n = 170)	Patients aged >65 years admitted to an acute medical care ward after a stroke Nutrition risk status assessed on admission using Malnutrition Universal Screening Tool (MUST) (Elia, 2003)	*Intervention* (n = 84) Received individualised nutritional treatment plan devised by MDT (ONS or tube feeding) during hospital admission and after discharge for 3 months *Control* (n = 86) Routine care i.e. ONS or tube feeding, at the discretion of the attending physician *Duration* Outcomes assessed at 3 months after study entry *Outcome measures* Weight Handgrip strength Quality of life (i.e. EuroQol-5D) Length of stroke-associated hospital stay Energy and protein intake Number of days waiting for transfer to rehabilitation facility or nursing home	124 (73%) completed the study (n = 46 failed to complete) *Weight* Fewer patients in intervention group lost ≥5% (20.7% versus 36.4%; P = 0.055) *Handgrip strength* Significant difference in change from baseline to follow-up in favour of intervention [2.3 (SD 3.7) versus −0.3 (SD 4.9) kg; P = 0.002] *Quality of life* Significant improvements in the intervention group in mobility, self-care and usual activities domains; between group differences not reported Note: questionnaires incomplete in 46 (27%) patients (23 intervention; 23 control) *Length of stay*: NS *Energy and protein intake* Significant difference in energy intake in favour of intervention [Intervention 5010 (SD 1376) kJ day^{-1} versus 4373 (SD 1268) kJ day^{-1}; P = 0.032] but no difference in protein intake	Computer-generated randomisation table; treatment allocation concealed in opaque envelopes; not blinded

CI, confidence interval; MDT, multidisciplinary team; NS, nonsignificant.

Table 4 Description of studies included for question A3: enteral nutrition via a gastrostomy versus via a nasogastric tube

Study	Study design	Participants	Intervention, duration and outcome measures	Results	Quality assessment
Gomes *et al.* (2010)	Cochrane systematic review and meta-analysis	9 Randomised controlled trials (RCTs); 686 adults with swallowing problems; variety of clinical conditions; four studies (Norton *et al.*, 1996; Bath *et al.*, 1997; Dennis *et al.*, 2006; Hamidon *et al.*, 2006) included stroke patients	*Intervention* Percutaneous Endoscopic Gastrostomy (PEG) tube *Comparison* Nasogastric tube (NGT) *Duration* Variable *Outcome measures* Mortality Intervention failure Pneumonia Complications Mean survival (months) Difference in weight (kg) at endpoint Weight change (kg) Difference in serum albumin at endpoint Reflux oesophagitis Length of stay (days) Modified Rankin score 4–5 Time of enteral nutrition (days) Patient satisfaction Inconvenience to nurses Mid-arm circumference (cm) at endpoint Functional ability (modified Rankin Score)	*Intervention failure* PEG associated with lower incidence of intervention failure RR = 0.24 (95% CI = 0.08–0.76); $P = 0.01$ *NS differences between PEG and NG in*: Mortality Pneumonia Complications Mean difference in: survival (months) 4.30 (95% CI = 3.28–5.32) weight at endpoint and weight change: NS – albumin (endpoint) 7.80 (95% CI = 5.52–10.08) length of stay (days): NS Modified Rankin Score 4–5: NS – time of enteral nutrition (days): NS – patient satisfaction scores: NS Mean difference in inconvenience to nurses score: NS – mid-arm circumference (cm) at endpoint: NS Reflux oesophagitis RR = 0.45 (95% CI 0.22, 0.92)	Majority of studies had a small sample size; patients were included with a variety of different clinical conditions; lengths of follow-up varied

CI, confidence interval; NS, nonsignificant; RR, relative risk.

agement) to promote independent and safe feeding as far as possible (RCP/ISWP, graded D)

A1.5 Fluid balance and nutritional intake should be monitored in all stroke patients who are at high risk of malnutrition, are malnourished and/or have swallowing problems (RCP/ISWP, graded D)

Practical considerations: Although the MUST is the example screening tool cited above, it should be noted that, to our knowledge, there are no published studies validating MUST or any other nutritional risk screening tool; for example, the Nutritional risk screening (Kondrup *et al.*, 2003), the Short Nutritional Assessment Questionnaire (Kruizenga *et al.*, 2005), etc., in a post-stroke population.

A2 In patients with acute stroke who are unable to consume adequate fluids orally and are assessed as at nutritional risk (using a validated method), does enteral nutrition via a nasogastric tube (NGT) reduce mortality and/or morbidity and/or improve functional status or quality of life compared to a texture modified diet (TMD)?

No RCTs were identified that met the inclusion criteria for this question. Currently, therefore, there is no evidence to support either method of enteral nutrition over the other. No evidence statement was developed for the stroke guidelines but dietitians are referred to the NICE guidelines for nutritional support in adults (NICE, 2006) where the following recommendations were made.

- People who present with any obvious or less obvious indicators of dysphagia should be referred to healthcare professionals with relevant skills and training in the diagnosis, assessment and management of swallowing disorders [NICE guidelines, graded D (GPP)]
- When managing people with dysphagia, healthcare professionals with relevant skills and training in the diagnosis, assessment and management of swallowing disorders should consider the risks and benefits of modified oral nutrition support and/or enteral tube feeding including the potential effects of other factors, such as level of alertness, vulnerability and dependence on others for feeding [NICE guidelines, graded D (GPP)]

Table 5 Description of studies included for question A4: the role of bridles and other restraints in patients receiving enteral nutrition via a nasogastric tube

Study	Study design	Participants	Intervention, duration and outcome measures	Results	Quality assessment
Beavan *et al.* (2010)	RCT (n = 104)	Dysphagic acute stroke patients for whom a nasogastric tube (NGT) was indicated after a standardised water swallow test Exclusions: Feeding via **NGT contraindicated or established for more than 7 days elsewhere	*Intervention* (n = 51) NGT secured using a nasal bridle *Control* (n = 53) NGT secured using conventional adhesive dressing *Duration* 2 weeks intervention; 3 months follow-up *Outcome measures* Primary outcome Proportion of prescribed feed and fluid delivered via NGT over 2 weeks Secondary outcomes 2 weeks Number of NGT insertions Weight change Treatment failure Tolerability Adverse events Costs 3 months Mortality Length of hospital stay Residential status Barthel score	Follow-up at 2 weeks; n = 104 (100%) Follow-up at 3 months; Intervention n = 35 (67%); Control n = 30 (57%) *Proportion of prescribed feed and fluid delivered over 2 weeks* Significantly greater in intervention group (mean difference 0.17%; 95% CI 0.05–0.28; P = 0.002) *Mean volume of feed and fluids delivered* Significantly greater in intervention group (5627 mL; 95% CI = 1976–9278; P = 0.002) *Costs* Mean costs higher in the intervention group (£426 versus £338 per patient over 2 weeks; P value not stated) *Number of NGTs passed.* Fewer in intervention group (median 1 versus 4; $P < 0.0001$) *Treatment Failure* Lower rate of failure in intervention group (25% versus 40%; P value not stated) *Adverse events* Higher rate of nasal trauma in intervention group (RR = 2.47; 95% CI = 1.3–2.7) Fewer electrolyte abnormalities in intervention group (31% versus 58%; P value not stated) No other significant differences between the groups at 2 weeks or 3 months	Long-term outcome in this patient group was poor [88/104 (84%) were either dead or severely disabled at 3 months] Randomisation method adequate; concealed allocation sequence; outcome assessments not blinded but data analysis was

CI, confidence interval; NS, nonsignificant; RR, relative risk.

Table 6 Description of studies included for question A5: feeding into the small bowel versus intragastric feeding

Study	Study design	Participants	Intervention, duration and outcome measures	Results	Quality assessment
Loeb *et al.* (2003)	Systematic review of RCTs of interventions to prevent aspiration pneumonia in older adults	8 randomised controlled trials (RCTs) in populations that included patients aged >65 years who were at risk for aspiration One trial (Park *et al.*, 1992); investigated dietary intervention in patients with a history of stroke or other neurological disease	*Intervention* Dietary interventions (n = 2); small bowel feeding tube placement (n = 1); continuous nasogastric feeding (n = 1); Percutaneous gastrostomy feeding versus nasogastric feeding (n = 1); pharmacologic therapies (n = 2); oral hygiene (n = 1) *Comparison* Placebo, no intervention, or another class of intervention *Duration* Variable *Outcome measures* Aspiration pneumonia Aspiration Dehydration Nutritional intake Mortality	One RCT (n = 33) assessed the effect of feeding into the small bowel compared to nasogastric feeding (Strong *et al.*, 1992) Differences between feeding into the small bowel versus nasogastric feeding in: *Aspiration pneumonia*: NS *Nutritional intake (Kcal)*: NS *Tube displacements*: NS	The one relevant study was assessed as being at high risk of bias as the study was small (n = 33) and no details were provided on the randomisation procedure

NS, nonsignificant.

Table 7 Description of studies included for question A6: texture modified diets (TMD) versus TMD + oral nutritional supplements and/or enteral tube feeding

Study	Study design	Participants	Intervention, duration and outcome measures	Results	Quality assessment
Foley *et al.* (2008)	Systematic review of dysphagia treatments after a stroke	15 randomised controlled trials in patients recovering from stroke and identified as dysphagic by the study investigators Four trials evaluated the effect of texture modified diets (Groher, 1987; Garon *et al.*, 1997; Goulding & Bakheit, 2000; Whelan, 2001)	*Intervention* Texture modified diet (n = 4), enteral feeding (n = 3); general dysphagia therapy programmes (n = 2); thermal therapy (n = 2); olfactory stimulation (n = 1); pharmacotherapy (n = 1) *Comparison* Placebo, no intervention, or another class of intervention *Duration* Variable *Outcome measures* Pneumonia Mortality Return of functional swallowing	Pooled analyses inappropriate asa result of heterogeneity of the interventions, as well as the timing and nature of the outcomes assessed	Studies were small and generally at high risk of bias due to inadequate blinding to treatment allocation and/or outcome assessment

NS, nonsignificant.

Practical considerations: The risks and benefits of earlier versus later removal of NGTs in patients on TMDs should be considered on a case by case basis. In particular, where early removal of NGTs occurs (or temporary withdrawal of enteral nutrition is planned as a means of stimulating an increase in oral intake), more frequent monitoring and follow-up should occur.

A3 In patients with acute stroke who are unable to consume adequate fluids orally and are assessed as at nutritional risk using a validated method, does enteral

nutrition via a gastrostomy reduce mortality and/or morbidity and/or improve functional status or quality of life compared to enteral nutrition via a NGT?

In addition to the three RCTs (Norton *et al.*, 1996; Dennis *et al.*, 2005a; Hamidon *et al.*, 2006) included in the 3rd edition of the guidelines (RCP/ISWP, 2008), one Cochrane systematic review met the inclusion criteria for this question (Gomes *et al.*, 2010). This Cochrane review had not searched all the relevant databases required by the GDG (i.e. Web of Science and Cinahl) and so additional searches were run on these databases by one of the search team (FG). No additional studies were identified.

The Cochrane review (Gomes *et al.*, 2010) reported data on nine RCTs in a total of 686 participants of varying clinical backgrounds, including four studies in patients who had dysphagia following a stroke (Norton *et al.*, 1996; Bath *et al.*, 1997; Dennis *et al.*, 2005a; Hamidon *et al.*, 2006). Although percutaneous endoscopic gastrostomy (PEG) was associated with a significantly lower probability of feeding failure [relative risk (RR) = 0.24; 95% confidence interval (CI) = 0.08–0.76], there was no significant difference between PEG and NGT in terms of mortality rates (RR = 0.96; 95% CI = 0.64–1.44) and pneumonia (RR = 0.84; 95% CI = 0.61–1.14), irrespective of the underlying clinical condition. The authors of the review noted the small numbers in each trial and the varying length of follow-up and concluded that more research is required to answer this question definitively. Taking into account the evidence and the relevant NICE guidelines (NICE, 2006), the following evidence statements were developed.

A3.1 Until a safe swallowing method has been established, all patients with identified swallowing difficulties should:

be considered for alternative fluids with immediate effect

be referred for specialist nutritional assessment, advice and monitoring

receive adequate hydration, nutrition and medication by alternative means (RCP/ISWP, graded D)

A3.2 People with acute stroke who are unable to consume adequate nutrition and fluids orally should be:

considered for enteral feeding with a NGT within 24 h of admission

considered for a nasal bridle tube or gastrostomy if they are unable to tolerate a NGT

referred to an appropriately trained healthcare professional for detailed nutritional assessment, individualised advice and monitoring (RCP/ISWP, graded D)

A3.3 Gastrostomy feeding should be considered for stroke patients who:

need but are unable to tolerate NGT feeding

are unable to swallow adequate amounts of food and fluid orally by 4 weeks

are at long-term high risk of malnutrition (RCP/ISWP, graded D)

Practical considerations: As a result of advances in clinical practice and evidence from the FOOD trial (Dennis *et al.*, 2005a), it is less common to initiate early PEG feeding (<4 weeks after an event) unless there is a clear clinical indication to do so (e.g. failure to tolerate enteral feeding via a NGT or meet full requirements orally).

The following recommendations for clinical practice from the NICE guidelines for nutritional support in adults (NICE, 2006) should be considered:

- People in general medical, surgical and intensive care wards who are malnourished or at risk of malnutrition and have inadequate or unsafe oral intake and a functional, accessible gastrointestinal tract should be fed via a tube into the stomach unless there is upper gastrointestinal dysfunction [NICE guidelines, graded D (GPP)]
- People who are malnourished or at risk of malnutrition and have inadequate or unsafe oral intake and a functional, accessible gastrointestinal tract with upper gastrointestinal dysfunction (or an inaccessible upper gastrointestinal tract) should be considered for post-pyloric (duodenal or jejunal) feeding [NICE guidelines, graded D (GPP)]
- Gastrostomy feeding should be considered in people likely to need long-term (4 weeks or more) enteral tube feeding [NICE guidelines, graded D (GPP)]

A4 In patients with acute stroke who are receiving enteral nutrition via a NGT, does a nasal bridle, mittens or other restraining device increase the length of time the NGT is *in situ* and reduce mortality and morbidity or prevent early feeding via a gastrostomy compared to not using any devices?

One small RCT of moderate quality met the inclusion criteria for this question (Beavan *et al.*, 2010). The study was conducted in 104 dysphagic stroke patients and showed that, although a nasal bridle significantly increased the amount of enteral nutrition and fluid delivered, ameliorated electrolyte disturbances and reduced NGT failure, no differences were seen in terms of mortality, morbidity, PEG placement, functional outcomes or length of stay at 3 months. The intervention period was limited to 2 weeks.

No RCTs were identified that evaluated the effects of mittens or other restraint devices.

The GDG concluded therefore that nasal bridles should be considered if NGTs need frequent replacement. The following evidence statement was developed in collaboration with the GDG.

A4.1 Until a safe swallowing method has been established, all patients with identified swallowing difficulties and receiving enteral nutrition via a NGT, should be considered for the additional use of a nasal bridle if the NGT needs frequent replacement. This should be undertaken using locally agreed protocols (RCP/ISWP, graded C)

Practical considerations: Although there was insufficient evidence to support a recommendation for the use of mittens, in centres where these are used, a locally agreed protocol should be in place to minimise the risk of associated complications. Training and reinforcement of good practice with regard to taping and securing NGTs should also be regularly carried out.

A5 In patients with acute stroke who require enteral tube feeding, does feeding into the small bowel reduce the risk of aspiration compared to intragastric feeding?

One systematic review (Loeb *et al.*, 2003) was identified that aimed to evaluate interventions to prevent aspiration pneumonia in older adults. Eight RCTs were included in the review. Four of these limited their inclusion criteria to those with a history of stroke or other neurological disease; however, only one small RCT ($n = 33$) of poor to moderate quality assessed the effect of enteral feeding into the small bowel compared to enteral feeding via a NGT on the incidence of aspiration pneumonia, nutritional intake and tube displacements (Strong *et al.*, 1992). In this study, no significant differences were observed between the groups in any of the outcomes. Currently, therefore, there is no evidence to support either route of feeding over the other. No evidence statement was developed.

Practical considerations: Post-pyloric feeding should be considered on a case by case basis where upper gastrointestinal dysfunction is suspected and in line with local medical and pharmacological treatment strategies. The following recommendations for clinical practice from the NICE Guidelines for adult nutritional support (NICE, 2006) should be considered.

- The initial placement of post-pyloric tubes should be confirmed with an abdominal X-ray (unless placed radiologically). Agreed protocols setting out the necessary clinical checks need to be in place before this procedure is carried out [NICE guidelines, graded D (GPP)]
- Where delayed gastric emptying occurs despite use of prokinetic agents, post-pyloric feeding and/or parenteral nutrition should be considered [NICE guidelines, graded D (GPP)]

A6 In patients with acute stroke who are unable to consume sufficient fluids orally and are assessed as at nutritional risk, does supplementing a texture modified diet with enteral tube feeding (nasogastric or gastrostomy) and/or oral nutritional supplements reduce mortality and/or morbidity and/or improve functional status or quality of life compared to texture modified diet alone?

One systematic review of RCTs was identified that aimed to evaluate the effect of a variety of dysphagia treatments after a stroke (Foley *et al.*, 2008), including four trials evaluating the specific effect of texture modified diets alone on dietary intake and/or nutritional status (Groher, 1987; Garon *et al.*, 1997; Goulding & Bakheit, 2000; Whelan, 2001). The authors of the review were unable to summarise the overall effect of the treatments as a result of the heterogeneity of interventions, timing and duration of therapy and stage of recovery of the trial participants. Currently, there is a lack of evidence to support the role of texture modified diets, either alone or in conjunction with ONS or enteral tube feeding, in maintaining or improving the nutritional status of dysphagic stroke patients. In collaboration with the GDG, and taking into account relevant NICE guidelines (NICE, 2006), the following evidence statements were developed.

A6.1 Until a safe swallowing method has been established, all patients with identified swallowing difficulties should:

be considered for alternative fluids with immediate effect
have a comprehensive assessment of their swallowing function undertaken by a specialist in dysphagia
be considered for NGT feeding within 24 h
be referred for specialist nutritional assessment, advice and monitoring.
receive adequate hydration, nutrition and medication by alternative means (RCP/ISWP graded D)

A6.2 Every stroke patient who requires food or fluid of a modified consistency should:

be referred for specialist nutritional assessment
have texture of modified food or liquids prescribed using nationally agreed descriptors (NPSA, 2012)
have both fluid balance and nutritional intake monitored (RCP/ISWP graded D)

3 Any stroke patient discharged from specialist care services with ongoing dysphagia should have their nutritional status and dietary intake monitored regularly by a suitably trained professional (RCP/ISWP graded D)

Practical considerations: As a result of the complex nature of dysphagia and the range of its presentations, the appropriateness of intervention in individual cases should take account of all ethical and legal considerations. Treatment decisions should always involve the patient, family and clinical teams.

Discussion

These guidelines provide evidence statements, recommendations and practical considerations for healthcare professionals involved in the nutritional support of patients who have had a stroke. There is a lack of stroke-specific

research in a number of key areas, although it would be sensible to assume the underlying principles of nutritional management of undernourished stroke patients are similar to those that underlie the management of other patient groups. In the absence of a robust evidence base, there is an urgent need for large, good quality observational studies and RCTs in a number of key areas, including but not limited to the Nutritional intake after stroke, Enteral nutrition, and Texture modified diets.

Nutritional intake after stroke

Given that malnutrition is a condition that develops over time, it is unclear how long poor nutritional intake needs to persist before an impaired nutritional status is manifested as a decline in outcome (e.g. increased risk of mortality and morbidity). Some patients have difficulties meeting their nutritional needs for many months after a stroke and weight loss is common in the short term as well as the long term (Jonsson *et al.*, 2008); yet there is a general lack of studies looking at the effects of longer-term nutritional support in patients who have had a stroke. Malnutrition can take some months to develop; thus, it may be unrealistic to assume that a short-term nutritional intervention (e.g. 1 week or only during the acute phase after stroke) is sufficient to treat any pre-existing nutritional deficiencies and/or improve outcomes. The ideal methods and routes of feedings are yet to be determined. Via the oral route, routine provision of ONS in stroke patients is not beneficial (Dennis *et al.*, 2005b); however, there is a general lack of evidence around the relative merits of ONS and food-based interventions, such as dietary counseling (Baldwin & Weekes, 2012).

Enteral nutrition

As noted above, there is a lack of evidence to support feeding into the small bowel over feeding into the stomach, in terms of reduction of the incidence of aspiration pneumonia and tube displacements, and improvement of nutritional intake in patients who had a stroke. Therefore, a robust study is needed to answer this question. Furthermore, it is not yet known which or how many stroke patients who are PEG fed are able to make the transition back to oral diets and what are the best strategies for managing these patients.

Texture modified diets

Modified texture diets are frequently used in patients with swallowing problems but the literature shows that these diets are nutritionally deficient, particularly in energy and protein (Wright *et al.*, 2005; Foley *et al.*, 2006). Other studies claim that supplemental enteral or parenteral fluids are necessary to achieve minimum fluid requirements in dysphagic patients (Vivanti *et al.*, 2009). These diets, if administered for prolonged periods, can lead to dehydration and malnutrition, with its associated consequences.

Currently, there is a lack of evidence on the role of texture modified diets (either alone, with oral nutritional supplements or in conjunction with enteral tube feeding) in improving outcomes of dysphagic stroke patients (NICE, 2006). Therefore, further studies are needed in this area.

Research recommendations

When designing a randomised controlled trial to evaluate nutritional support after stroke, it is important to ensure that populations are homogeneous, such as for age, type of stroke (e.g. ischaemic versus haemorrhagic), stroke severity (as assessed by a validated scale e.g. the National Institute of Health Stroke Scale), ethnicity, etc., because these are factors that may influence the outcomes. Outcomes need to be nutritional (e.g. dietary intake and weight change), patient-centred (e.g. functional status or quality of life), clinical (e.g. morbidity, mortality) and also of importance to health and social care organisations (e.g. hospital admissions and length of hospital stay, and cost effectiveness). The classification of patients who are malnourished or at risk of malnutrition needs to be systematically conducted with a validated method, to correctly identify those who are more likely to benefit from nutritional support interventions. Indicators of inflammatory response, such as albumin and prealbumin, have been used in the past in nutritional assessment but they should be interpreted with caution; for example, the hepatic production of these two proteins is known to be down-regulated during periods of acute illness, independent of nutritional status (Gabay & Kushner, 1999). Indeed, a recent consensus statement of renowned institutions does not propose any specific inflammatory markers for diagnostic purposes of adult malnutrition (White *et al.*, 2012). There is a lack of evidence to support the role of nutrition screening tools in the management of malnutrition in stroke and this is an area that has been identified as requiring further research (Scottish Intercollegiate Guidelines Network, 2010). Nutritional interventions need to be fully described, including the duration and intensity of nutritional support, and, when compared with usual care, it is essential to detail what constitutes this usual care. This is particularly important because randomising patients identified as being malnourished to less than optimal treatment may be problematic.

It should be noted that this work was conducted as part of the process to develop the 4th edition of the RCP/ISWP 'National Clinical Guideline for Stroke' and this paper reflects the impact of multidisciplinary discussions and interpretation of results by the GDG of the RCP/ISWP. A limitation of this review is that the literature searches have not been updated since October 2011. Therefore, these guidelines only provide evidence-based recommendations based on the publications available until that time point. The 5th edition of the RCP/ISWP 'National Clinical Guideline for Stroke' will be published in 2016.

In conclusion, this review summarises the updating process of the national guidelines on nutritional support after stroke, offering recent evidence-based recommendations for clinical practice and identifying areas that merit further research.

Acknowledgments

The authors thank Helen Armitage, Preetpal Atwal, Angeline Bonney and Berenice Carter for their assistance in the quality review of some of the included papers.

Conflict of interests, source of funding and authorship

The authors declare that there are no conflicts of interest. The present review received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.
FG helped to define the search terms, conducted all literature searches, undertook some quality review and contributed to the preparation of this manuscript. CH identified search questions, helped to define the search terms, undertook some quality review and reviewed this manuscript. CEW identified search questions, helped to define the search terms, reviewed all abstracts, undertook some quality review and led with regard to the preparation of this manuscript. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Data S1. Online supplement with search terms used for literature searches conducted in five electronic databases.

